



REMARKS

This is a Response to the Office Action mailed August 23, 2005. Claims 1-42 are pending and again respectfully submitted for consideration.

Claims 1-42 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Published Patent Application No. 2001/0031999 (*Carter et al.*). The grounds for the rejection are set forth on pages 2-5 of the Office Action. The Office Action also cited U.S. Patent Nos. 4,598,173 (*Hansjurgens et al.*); 4,848,347 (*Hall*); 5,107,835 (*Thomas*); 5,215,086 (*Terry et al.*); 5,269,304 (*Matthews*); and 5,76,173 (*Madsen et al.*), but none of those references were applied. The rejection of claims 1-42 is respectfully traversed according to the remarks that follow.

The present invention is directed to a stimulator and a method for the treatment of intractable pain syndromes by electrical stimulation in target areas by implantable electrodes positioned therein. Claims 1 and 15 recite, in part, “at least *two pairs of implantable electrodes* ... [which] ... interfere with each other to produce *at least one beat frequency signal*.” Claims 9, 12, 23 and 26 recite, in part, “*two pairs of implantable electrodes* [which] interfere to produce *at least one beat frequency signal*.” Claims 29 and 37 recite, in part, “positioning said *first pair of implantable electrodes*” and “positioning said *second pair of implantable electrodes*” and “so that the first and second frequencies interfere to create *at least one beat signal proximate to the targeted area*.”

Carter et al. is directed to an electro-therapy apparatus and method for providing therapeutic electric current to a treatment site of a patient, having means for providing two oscillating or pulsing electric alternating currents, of frequencies which differ from each other by as little as 1 Hz and up to about 250 Hz, but each being of frequency at least about 1 KHz. The apparatus and method requires *only one* feed electrode adapted to feed the electric

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currents to selected feed sites on or beneath the epidermal or mucous surface of the patient, and *only one* return electrode. It is clear from the disclosure in *Carter et al.* that the electrodes would not be attached to the dura mater (below the bone) in the epidural space of the patient or in close proximity thereto. The system uses the composition of the patient's body to produce a mixing of the independent frequency signals to create an interference signal which is alleged to provide a beat frequency signal.

The Office Action cites *Carter et al.* as teaching all of the elements of claims 1-42, save a single element. The Office Action acknowledged that *Carter et al.* fails to teach all of the elements of the independent claims and argues that a modification of *Carter et al.*, such that it uses multiple pairs of electrodes, would have been obvious. Applicants respectfully traverse the rejection as being improper for failing to teach or suggest all of the elements of the claims and that the proposed modification of *Carter et al.* makes the intended rejection improper.

First, as discussed above, all of the independent claims recite "implantable electrodes." *Carter et al.* discloses that the electrodes feed the electric currents to selected feed sites on or beneath the epidermal or mucous surface of the patient. The term "implantable," as used in the specification and in common use in the art, applies to electrodes that are applied within the body with no intent to remove, not just on or beneath the epidermal surface. These are different from the electrodes in *Carter et al.* that are disclosed to be pads and are not disclosed as being "implantable." As such, Applicants respectfully assert that *Carter et al.* cannot teach or suggest such implantable electrodes based on its disclosure, and the rejection of claims 1-42 should be withdrawn as being improper.

Carter et al. does not disclose spinal cord stimulation or dorsal column stimulation whereas, the present application recites that "[a] first pair of implantable electrodes 108, 208

are positioned on a subject's spinal column 112, preferably the dorsal column, at one set of diagonal corners of a targeted area 214. A second pair of implantable electrodes 108, 208 is then positioned at the other set of diagonal corners of the targeted area 214. Preferably, the electrodes 108 are attached to the dura matter in the epidural space." See specification, paragraph [0018]. The claims have been previously amended to recite that the implantable electrodes are "adapted to be located at predetermined locations proximate to a subject's spinal cord" and "adapted to be positioned proximate to a subject's spinal cord at predetermined locations." As such, Applicants respectfully assert that this element of the claims is also neither taught nor suggested by *Carter et al.*

Additionally, the "beat frequency signal" provided in *Carter et al.* is not a beat frequency as described and claimed in the present invention. The formation of a beat frequency signal through interference of separately applied signals is illustrated in Fig. 1 of the present specification. The "beat frequency" in *Carter et al.* is described in paragraph [0034], where "[t]he Feed Signals are exponentially multiplied by materials within the body giving rise to a low frequency component, the beat frequency, in the form of an electric field within the volume of tissue defined by the geometry of the body between the electrodes." It is not clear, however, that this low frequency component would be the same the beat frequency described and claimed in the independent claims. As such, Applicants respectfully assert that *Carter et al.* cannot teach or suggest a beat frequency produced by signals of different frequencies based on its disclosure, and the rejection of claims 1-42 should be withdrawn as being improper.

In addition to the elements that Applicants respectfully assert are neither taught nor suggested by *Carter et al.*, Applicants also respectfully assert that the modifications proposed in the Office Action would render *Carter et al.* unsatisfactory for its intended purpose, would

change the principle of operation of *Carter et al.* and fails to consider *Carter et al.* in its entirety, including portions that teach away from the claims.

Carter et al. also espouses the benefits of having only a single pair of electrodes, as opposed to disclosed prior art systems that have multiple pairs of electrodes. Paragraph [0059] recites that “TENS type apparatuses suffer from the need for multiple electrodes and power amplifiers for each signal channel. As the number of signals increases, so do the demands on electrode placement and circuit design.” Paragraph [0060] recites that “[i]n system with feed signals fed through multiple feed electrodes the paths can vary greatly, altering the fidelity and bioelectric characteristics of the resultant signal,” and that “[t]he use of a single signal feed causes the outcome of these variables to impact all the desired signals in parallel. This effectively nullifies the problems that arise from the differential effects that arise when multiple variables impact multiple signals independently.” As such, *Carter et al.* expresses a clear preference for a single pair of electrodes and discloses the relative disadvantages of using more than two electrodes.

The Office Action, at page 3, provides that the “Examiner takes the position that it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the system taught by Carter to include at least two pair [sic] of implantable electrodes, since it is well [sic] in the art that such a configuration is well known to provide efficient and effective stimulation.” However, such a change would render *Carter et al.* unsatisfactory for its intended purpose, would change the principle of operation of *Carter et al.* and fails to consider *Carter et al.* in its entirety, including portions that teach away from the claims.

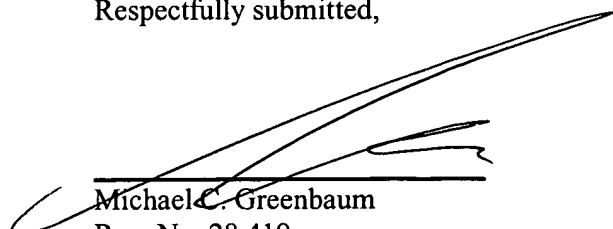
Given the above referenced discussions of *Carter et al.*, the system described therein would not likely work with multiple pairs of electrodes and would at least not work with the reliability discussed in *Carter et al.* Also, given that *Carter et al.* discloses the use of the

body's structure to produce a beat frequency with a single pair of electrodes, the inclusion of multiple pairs of electrodes would have to change the principle of operation of *Carter et al.* Lastly, given the disadvantages of the multiple electrode systems discussed in *Carter et al.*, this portion thereof would teach away from the proposed modification suggested in the Office Action. As such, Applicants respectfully assert that the rejection of claims 1-42 as being obvious in view of *Carter et al.* is improper and should be withdrawn.

Reconsideration and withdrawal of all rejections are respectfully requested and a Notice of Allowance is earnestly solicited. If a telephone or personal conference would expedite prosecution, the Examiner is invited to contact the undersigned, who will cooperate appropriately to advance the case.

Please charge any deficiency in fees, or credit any overpayment thereof, to BLANK ROME LLP, Deposit Account No. 23-2185 (000309-00053). In the event that a petition for an extension of time is required to render this submission timely, Applicants hereby petition under 37 C.F.R. § 1.136(a) for such an extension for as many months as are required to render this submission timely, and request that the PTO charge the extension fee to the deposit account as authorized above.

Respectfully submitted,



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